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MDS Nordion
Science Advancing Health

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July 20, 1999

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville MD
20852

Dear Sir or Madam:

Subject: Proposed Rules – Foreign Establishment Registration and Listing

As per instructions in the Federal Register, Vol 64, No 93, pp 26330-26344, we provide the following comments on the proposed rules for establishment listing and registration.

1. Section III, Analysis of Impacts (p 26338) provides an estimate of the costs of registration to small businesses outside the U.S. and concludes that the cost is minimal. However, this analysis is based purely on the time required to fill out a registration form, and ignores the additional expense introduced by the requirement to have a U.S. agent. Firms that are too small to have a permanent U.S. address will be required to hire a representative, who will most likely charge an annual retainer and a substantial hourly or daily rate for services rendered. The cost analysis should be revised to reflect this burden, along with an appraisal of whether the additional cost results in equivalent or greater benefit.

2. The requirement for a U.S. agent is advanced without any regard for whether it is truly needed, and for many foreign firms will result in additional expense with no value added either for the Agency or for the firm. Many foreign device and drug manufacturers have long-standing histories of good communication with the Agency, and identifying a U.S. agent adds no benefit, only cost. The application of this requirement should be modified to allow for no such agent being required in the cases where such a relationship has already been established.

We hope these comments are useful, and look forward to the publication of a response.

Sincerely,

E. S. Martell
Vice President
Quality & Regulatory Affairs

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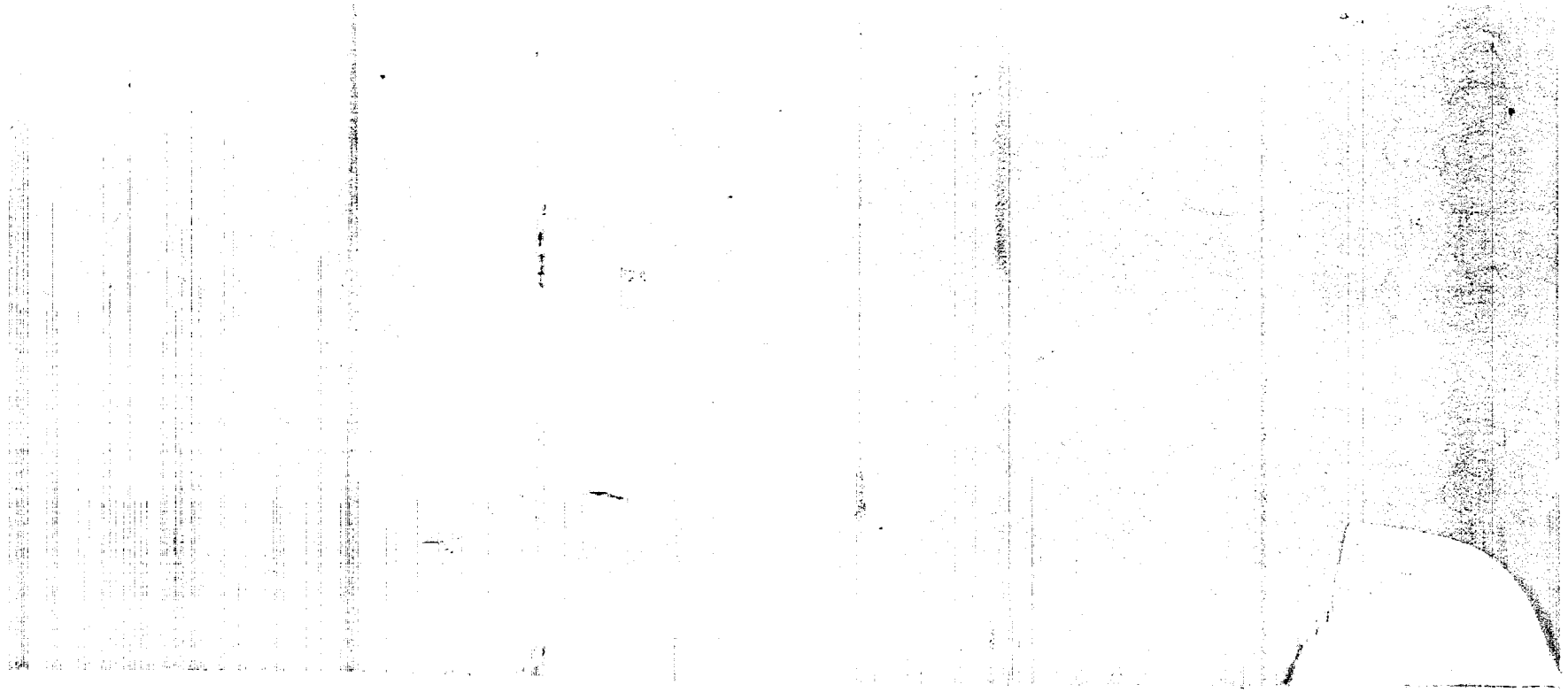

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